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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YU, MISOOK	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,356	CHEEVER ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *113-144* is/are pending in the application.

4a) Of the above claim(s) *126-144* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *113-125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☒ Interview Summary (PTO-413) Paper No(s). *14* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group 1, drawn to method using SEQ ID NO:6 in Paper No. 12 is acknowledged. Applicant's request for rejoining groups 1-4 is noted. On reconsideration, group II and III are rejoined because group II is drawn to method using SEQ ID NO: 7 protein, a fragment of SEQ ID NO:6, and group III is drawn to CpG-containing oligonucleotide, adjuvant instead of an active ingredient. However, groups IV is not be rejoined. Applicant's traversal is on the ground(s) that searching all pending claims would not have place an undue burden on the Examiner and the groups have the same inventive concept. This is not found persuasive because the search places an undue burden on the Examiner for the reasons set forth at pages 2-3 of the previous Office action mailed on 03-14-2003. Inventive concept in restriction does not apply to the instant case because it is not a 371 case.

The requirement is still deemed proper and is therefore made FINAL.

As for claim 126 not included in the Restriction Requirement mailed on March 04, 2003, it belongs to a different invention, group V drawn to method administering ex vivo treated cells to patient (as explained during phone interview on December 11, 2003 with Ms. Patent) because claim 126 is drawn to method administering ex vivo treated cells to patient instead of protein as in the case of the elected invention of group I. Applicant stated that instead of receiving another Restriction Requirement, claim 126 being withdrawn from the examination on merits is accepted.

Claims 126-144 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 113-144 are currently pending.

Claims 113-125 are examined on merits.

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 113-144 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 113 recites "**HER-2**" in line 2 and "**Her2**" in lines 3, and "**Her-2**" in line 4-5, 4, 5, and 6 but it is not clear what the metes and bounds are. This rejection affects all dependent claims. For the purpose of this Office action, the Office will assume all three mean a same protein known also as "neu". The specification originally filed uses "**HER-**

2". Therefore the Office will assume **Her2** and **Her-2** are same as **HER-2**. However, this treatment does not relieve applicant the burden of responding this rejection. Claim 123 recites "3dMPL" but it is not clear what the metes and bounds are. The specification at page 51 lines 20-21 discloses "3D-MPL" is 3-de-o-acylated monophosphorylated lipid A. However, the specification does not describe what "3dMPL" is. For the purpose of this Office action, the Office will assume the limitation means 3-de-o-acylated monophosphorylated lipid A. However, this treatment does not relieve applicant the burden of responding this rejection. Claim 124 is rejected because it depends on the rejected claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 113-125 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection based on the limitation "under stringent conditions to the complement of a nucleic acid sequence encoding an amino acid sequence of SEQ ID NO:6, wherein the hybridization reaction is incubated in a solution comprising 5x SSE at a temperature of 50-65 °C and washed in a solution comprising 0.2x SSC and 0.1% SDS at a temperature of 65 °C," in the base claim. This rejection affects all dependent claims.

The specification at pages 11, lines 13-30 says that stringent conditions depend on many different conditions such as how big the nucleic acids are on, so forth, then goes on describing exemplary stringent conditions in the paragraph bridging page 11-12. The specification originally filed does not convey "stringent conditions" is the specific conditions recited in the instant base claim. Applicant is requested for the support for the limitation in the specification as originally filed since the Office is unable to find the support.

Claims 113-144 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is made because the specification at page 7 lines 26- 28 states the limitation "HER-2/neu ECD-PD" also encompasses a protein from homologs, therefore the claims are interpreted as drawn to method of using a genus of polypeptides from various other species.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a human sequence. The specification does not teach the chemical structure of other homologs.

The specification does not teach that applicant has discovered any new homolog from different species. Instant SEQ ID NOs 6, and 7 are fragments of human HER-2/neu. It does not appear whether monkey has counter-part homolog, if it does, the chemical structures of such homolog is not known yet. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics of the proteins from homologs, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, given that the specification has only described SEQ ID NO: 6, 7. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is separable from its enablement provision (see page 1115). A definition by function alone "does not suffice, to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lily*, 119 F.3 at 1568, 43 USPQ2d at 1406.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 113, 114, 118, and 121 are rejected under 35 U.S.C. 102(b) as being anticipated by Disis et al (IDS, 1996, The Journal of Immunology, vol. 156, pages 3151-8).

The claims are interpreted as drawn to method of inducing immune response using any fragment from a HER-2/Neu ECD-PD protein excluding substantial portion of a transmembrane domain of said protein in the form of a vaccine (claim 114), along with physiologically acceptable carrier or diluent (claim 118), and an immunostimulatory substance (claim 121). The claim interpretation is based on the definition of the limitation "a HER-2/Neu ECD-PD fusion protein" at the specification at page 7 lines 12 to page 8 lines 16, says that the limitation includes any fragment as long as said fragment does not include a substantial portion of HER2/neu transmembrane domain.

Disis et al teach method of inducing immune response using various fragments from a HER-2/Neu ECD-PD protein excluding substantial portion of a transmembrane domain of said protein (note Table 1 at page 3153) in the form of a vaccine (note the title), along with physiologically acceptable carrier or diluent (claim page 3152, left column, the paragraph under the subtitle "Immunization"), and an immunostimulatory substance (note line 3 of the paragraph under the subtitle "Immunization" the word "adjuvant"). Thus Disis et al teach instant claims 113, 114, 118, and 121.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 117, 119, 120, 122-125 are rejected under 35 U.S.C. 103(a) as being unpatentable over Disis et al (IDS, 1996, The Journal of Immunology, vol. 156, pages 3151-8) as applied to claims 113, 114, 118, and 121 above, and further in view of applicant's admission at page 51, line 19 to line 31 of 52.

The claims are interpreted as drawn to vaccine adjuvant and/or formulations used in method of inducing immune response: claim 117, lipidated; claim 119, oil in water emulsion; claim 120, tocopherol; claim 122, 3D-MPL, QS21, or a combination of 3D-MPL and QS21; claim 123, 3D-MPL and QS21 in an oil-in water emulsion; claim 124, 3D-MPL, QS21 with tocopherol; claim 125, a CpG-containing oligonucleotide.

Disis et al do not teach the specific adjuvant and/or formulations recited in the instant claims. However, the specification teaches at page 51-52 all of the formulations and/or adjuvant have been described before the effective filing date of the instant application, for example, that oil in water emulsion, tocopherol, 3D-MPL was disclosed in EP 671 948..

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to formulate the vaccine of the base claim in known vaccine formulations and/or adjuvant with a reasonable expectation of success.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
December 12, 2003